MEETING

CALIFORNIA AIR RESOURCES BOARD

SCIENTIFIC REVIEW PANEL

HEARING ROOM

CALIFORNIA AIR RESOURCES BOARD

2020 L STREET

SACRAMENTO, CALIFORNIA

MONDAY, APRIL 18, 1994

10:20 A. M.

Nadine J. Parks
Shorthand Reporter

PETERS SHORTHAND REPORTING CORPORATION
3336 BRADSHAW ROAD, SUITE 240, SACRAMENTO, CA 95827 / (916) 362-2345

MEMBERS PRESENT

Dr. James Pitts, Chairman
Dr. Charles Becker
Dr. Gary Friedman
Dr. John Froines
Dr. Stanton Glantz
Dr. James Seiber
Dr. Hanspeter Witschi

Air Resources Board Staff:

Dr. Joan Denton
Genevieve Shiroma
Alex Krichevsky
Bill Lockett
Bruce Oulrey

Office of Health Hazard Assessment Staff:

Dr. George Alexeeff
Dr. Lauren Zeise
Amy Dunn

Also Present:

John Lagarias, Member
Air Resources Board

I N D E X

INDEX, continued

INDEX, continued. . .

INDEX, continued. . .

--o0o--

P R O C E E D I N G S

--o0o--

CHAIRMAN PITTS: Good morning. I presume this is on (speaking of microphone). Can you hear me in the back of the room? Are we okay? Thanks.

Since I'm nearsighted, I'm not sure whether I should put my glasses on to say hi to you people back there. Okay. But I've got some trusty bifocals. Actually, when you get to the stage when you use trifocals, you do that when you're in deep trouble. But as long as you're around long enough to even want to use them, that's the good news.

We'll begin the meeting today, then.

The first item on the agenda, SRP consideration of the Air Resources Board/OEHHA revised report, entitled "Benzo[a]pyrene as a Toxic Air Contaminant."

Genevieve, I'll turn it over to you.

MS. SHIROMA: Yes, thank you. Dr. Pitts, members of the Panel, welcome to Sacramento. We have nice weather for you today.

We are here today to discuss BaP with you. At the last SRP meeting, you asked that a number of clarifications be made to the Executive Summary, Part A, and Part B.

You also asked that additional health information be added to the Part B. So, we did that, and we put the materials out for public comment. We received one letter.

And Alex Krichevsky will be discussing the changes made to the Part A and the Executive Summary, and George Alexeeff will discuss the Part B.

So, with that, I'll turn it over to Alex.

MR. KRICHEVSKY: Good morning, Dr. Pitts. Good morning, Dr. Froines, and members of the Scientific Review Panel.

Today, I will briefly summarize the revisions and clarifications which you requested us to make to the report. These are contained in your package, and I will go through them in order.

First, in response to Dr. Seiber's comment, throughout the report, certain technical terms have been defined or clarified. For example, the term "agricultural and other waste burning" was replaced with the term "vegetative materials burning."

Next, in response to Dr. Witschi's comment, the OEHHA staff provided the information on uncertainties involved in the risk assessment development. We have added a clarifying paragraph to the Executive Summary and Part B.

In response to Dr. Pitts' comment, we calculated and added to the Executive Summary an estimate of combined risk of exposure from four PAHs other than BaP. In addition, we also added a new paragraph to the Executive Summary and to the Part A, which discusses the mutagenicity

of BaP and other PAHs emitted or formed in the atmosphere and which contribute to the total mutagenicity of ambient air.

Dr. Froines requested that we clarify the exposure to BaP through drinking water in California. We have changed a sentence on page 7 of the Executive Summary and on page E-22 of Appendix E to conclude that there are insufficient data to determine exposure to BaP through drinking water in California. We also calculated cancer risk from indoor exposure to BaP and included this information in the Executive Summary, Part A, and Appendix E.

There were several editorial changes made to the Part A. For example, the list of appendices, list of tables, and list of figures have been changed to reflect the corrections and clarifications made.

Dr. Glantz requested us to clarify that the sources of BaP in Table III-1 in order of emissions, not of exposure. We have added a footnote "a" to this table to reflect that.

Dr. Friedman and Dr. Glantz had questions on Figure IV-4, page A-35 on the percentage of population exposed to the statewide population-weighted exposure or above. The description in the text was revised.

I would also like to point out that we updated the

indoor portion of the Part A and Appendix E.

We updated these portions of the report to include the latest Sheldon 1993 study on BaP concentrations indoors from different indoor combustion sources in Northern California.

The last area of revisions is in the Part C Addendum. At the last SRP meeting, we responded orally to comments received on the SRP version of the report. The written responses to comments have been added to Part C of the report and several clarifying sentences, per Dr. Roberts' comments, were added to Part A.

We also received one more comment from Dr. Roberts during this comment period. Dr. Roberts provided additional references on indoor concentrations of BaP and house dust. We will be adding these new references to the Part A per his comment.

This concludes my presentation. If the Panel has any questions, we would be happy to answer them at this time. Otherwise, I would like to turn over the microphone to Dr. Alexeeff, who will be summarizing the revisions to the Executive Summary, the Part B, the Health Assessment, and the Part C of the report.

CHAIRMAN PITTS: I think it's open for discussion now from the Panel. Are there comments on the additions, modifications to -- this is on Part A. Now, we haven't, by

the way, gotten to the Executive Summary. Shall we do that last, then? I have some suggestions to the summary.

MS. SHIROMA: Sure.

CHAIRMAN PITTS: Let's do that after we've gone through these --

MS. SHIROMA: Right.

CHAIRMAN PITTS: -- because that way, we can sort of summarize our discussion.

Anyone on this Part A? Okay. Yes, go ahead, Gary.

DR. FRIEDMAN: This is very minor, but on page A-8, I found the abbreviation "POM" that I don't think we've ever defined. Maybe I missed where it was spelled out. But if it wasn't spelled out anywhere, it would be good to do it there.

CHAIRMAN PITTS: POM?

DR. FRIEDMAN: Yeah.

CHAIRMAN PITTS: Yeah. Actually on that, I might comment. That, officially, is particulate polycyclic organic matter. The original definition of POM was particulate polycyclic organic matter. So, we want to be somewhat careful. If you've got five rings or more, it's going to be particulate. If you've got four rings in a PAH, it's semivolatile. So, it's part in the gas phase and part particulate.

And when you get three rings and below, it's primarily in the gas phase.

That is a term that indicates it's particulate polycyclic organic matter. That's a summary of various constituents, not only the PAHs, but the acridines, carbazoles, and other species. Yes, Dr. Glantz.

DR. GLANTZ: I just wanted to say for the record I was satisfied with the revisions to Part A. I thought you did a nice job.

CHAIRMAN PITTS: Are there other comments?

DR. SEIBER: Yeah, I just had a question about the woodburning smoke. There were quite a few changes made in Section E on woodburning smoke emissions.

Does that reflect new studies that had come to light after the first draft? Just for example, there's underlined paragraphs on E-11, and I was just wondering if that was because there were new studies or whether it's simply --

MR. KRICHEVSKY: That's correct.

DR. SEIBER: Okay. I was quite impressed with the new studies. It gives us a lot more information. I think that's a useful addition.

But I'm still a bit confused on woodburning stoves; with the very latest models that are on the market, is there or is there not any significant increase in BaP

emissions? If you used a brand new, state-of-the-art woodburning stove, according to all the installation and regulation codes, would there be a measurable increase? I read through this a couple times, and I couldn't quite figure it out.

DR. DENTON: Dr. Seiber, at this point, this information is kind of a baseline. And we don't know really. We need more testing on this brand new and air tight.

DR. SEIBER: Okay.

CHAIRMAN PITTS: I'd like to make one comment. On page A-9, in the underlined portion in the second paragraph at the bottom, it says, "BaP is also present in exhaust emissions from diesel and spark ignition engines. With the introduction of catalytic converters in 1974. . ."

First of all, wasn't that the first in California? I mean, did California lead the EPA by two years? Wouldn't that be 1974 "in California"? We ought to check that.

DR. DENTON: I think that you're correct.

CHAIRMAN PITTS: I think there was a two-year lag time and California had put in first the oxidizing catalyst. And then it was two years later than the federal did.

And then, where it says, "mobile source emissions of BaP were reduced," you really mean, then, mobile source emissions of BaP from light-duty motor vehicles, because the

diesels are unaffected by that.

DR. DENTON: Okay.

CHAIRMAN PITTS: I think we can figure out what we're saying here, on page A-11, I will not make it a major point of possibly you split an infinitive in the first line.

A-41, sorry, A-41. I got the wrong page, so you split an infinitive and I got the wrong page, so it's a draw. How's that? I thought that was somewhat humorous, but perhaps not.

You say, "It is not possible to precisely determine the reason for elevated BaP concentrations in Quincy and Mammoth." That's my major point.

And, then, down below, you say here, "Intensive woodburning for residential heating. . .is a major source of BaP emissions."

Wasn't that one of the reasons why they're elevated in Mammoth? Because it was wintertime and there was residential woodburning?

DR. DENTON: That's correct, Dr. Pitts.

CHAIRMAN PITTS: So, you might want to clarify that it is possible, or at least it may be a major contributor.

DR. DENTON: Okay.

CHAIRMAN PITTS: Well, I would like to join Dr. Glantz, and I think the rest of the Committee. I think the

revisions in Part A have been very useful. And we appreciate the efforts on this. After those very minor comments, we'll pass on to Dr. Alexeeff.

DR. ALEXEEFF: Okay. Hello, my name is George Alexeeff. I'm with the Office of Environmental Health Hazard Assessment.

I'm sorry, Dr. Collins couldn't be here to complete his presentation of the BaP, but he had to go out of town on business.

I would like to go through the changes that were made to the document, you know, some of the areas that were pointed out at the last meeting.

In the summary section, page 1-3, some additional language was added to indicate some of the difficulties with the study that was used in the risk assessment, some of the quality -- describing the quality of the study a little bit more in the summary.

In Section 5 -- I'll just go through numerically-- starting on page 5-2, the section on whole animal toxicology, a section was added discussing cardiovascular toxicity of benzo[a]pyrene, with an inclusion of a number of studies and identification of the lowest observable adverse effect level.

And, then, on -- that was primarily in response to Dr. Glantz' request.

Then, on Section 6 -- I think it was Dr. Friedman or Dr. Witschi, one or the other or both, suggesting to add some more information to the human studies epidemiology section, and to bring in the foundry worker health issues, and to tie that into giving us a total sense of the health effects of BaP. And that was done in Section 6, Section 6-1, and 6-3, a couple sentences added here and there.

And, then, on page 6-4, some more discussion of the key studies were added.

DR. FROINES: Did you question, George -- did you take the DNA adduct work that you added and then compare that with what you predict from toxicology/epidemiology in the risk assessment?

In other words, Fred Kadlubar, where he looked at the adducts that had been formed and using that as a basis for the risk assessment as opposed to the other doses

DR. ALEXEEFF: Right. No, we did not do that. The adduct information that we have in this case, sort of in contrast to what we had in the formaldehyde risk assessment. We had adduct information that directly related to the animal study, of which the risk assessment was based, and we could sort of improve the risk assessment on that basis.

Instead, this -- the way we saw this data, this adduct data was essentially in human studies, in human tissues, where the exposure was not as well quantified. And

the risk assessment is actually based on animal studies.

So, it's used more on a qualitative basis as opposed to quantitative. But it certainly would suggest that if further -- another study was done with BaP in animals, that -- adducts, excuse me, we can begin to find it in humans exposed.

And, then, there is the other weakness of the adduct studies, you know, the complication of where the actual exposure came from for the adducts, and that the adducts are kind of a marker; but, at the same time, it's hard to really pinpoint the exact compound it originated from or the exact source. So, there's that difficulty.

And in the quantitative risk assessment section, which is Section 7, some additional information was added, you know, regarding the cardiovascular effects, under noncancer effects. And, then, another section was added on page 7-17, adding more discussion of the uncertainty, uncertainty in the risk assessment estimates.

And, then, on Table 7-12 now, which is page 7-31, there was a correction made in the potency factor.

And, then, in the reference section, a number of references were added that came from the cardiovascular studies and the human epidemiology studies.

And, then, in the appendix, there is page A-2 or so and page A-5, there's the clarification of the correction

that was made that just fed into that table, 7-12 I guess it was.

So, that summarizes the changes that were made.

CHAIRMAN PITTS: Gentlemen? Start over here.

DR. BECKER: I think it's good.

DR. WITSCHI: A few minor things on page 1-1 of the summary, in the second paragraph, I still would like you to change "alkylate" DNA to "arylate" DNA.

Page 5-5. I also recognize a spelling error of Phalen, a-l-e-n. He's also my friend. The bottom line.

DR. ALEXEEFF: Oh, okay.

DR. WITSCHI: On page 6-4, about the middle of the page --

(Thereupon, the reporter requested Dr. Witschi use the microphone.)

DR. WITSCHI: You have "Perera, et al.," about the middle of the page. Okay, it's, "PAH-DNA adduct levels and mutation frequency at the hypoxanthine guanine phosphoribosyl transferase locus in their lymphocytes, the type of correlation consistent with cancer initiation."

I think that's overinterpreting.

DR. ALEXEEFF: Okay.

DR. WITSCHI: Because I don't think there's any evidence it has something to do with cancer initiation, so I'd just leave out.

DR. ALEXEEFF: Okay. We'll leave out the last clause, then.

DR. WITSCHI: That's all.

CHAIRMAN PITTS: Dr. Glantz?

DR. GLANTZ: Well, I think you did a nice job. All the things I was concerned about I thought were incorporated. So, I don't have anything.

CHAIRMAN PITTS: Dr. Friedman?

DR. FRIEDMAN: I don't have anything specific, except to second Stan's comments on the quality, good quality of the improvements on both Part A and Part B.

CHAIRMAN PITTS: Dr. Froines? Dr. Seiber?

DR. SEIBER: I'm happy.

CHAIRMAN PITTS: I'm also happy as a mere atmospheric chemist. But I would also make one comment that I noted on 6-1 that, on occasions that I have -- some of us have indicated that the references to the literature have not really been up to date. And I want to congratulate George and your crew on having a reference in here -- although it's not specifically cited -- to Sir Percival Pott in 1775. I think that's a winner.

Actually, it was published in Paralogical Observations, and you're familiar with the article, I'm sure. But I think it's a fine job. Thank you very much.

I think that takes care of Part B.

Part C?

DR. GLANTZ: Oh, Part C, okay. Well, this is sort of a way into Part C. I also just wanted to say I thought that the staff did a good job of incorporating the public comments into the text, too, which is an ongoing theme at these meetings as to whether or not the public comments are noted.

And I think you did a good job of adding the things that they suggested in revising the document when it was justified.

CHAIRMAN PITTS: Thank you. I think we all concur with that. Dr. Froines?

DR. FRIEDMAN: I just want to make one comment that I think that, as we move along on the diesel exhaust document, that we're going to need to look at the relationship between these individual chemical risk assessments and what risk we predict from diesel and other mobile sources, because we -- this is a single chemical issue we have here, and we're clearly going to a complex chemical mixture with diesel and others. And, so, we're going to need to pay attention to any relationship between the two, I think.

CHAIRMAN PITTS: Thank you. Any other comments. Then, any comments on Part C from the Panel members?

I'll go around the table. Do you have any

comments?

I would just ask one question here. The input from Dr. Roberts on the dust -- the dust problem, I saw you included that in several parts of your discussion. I'm not sure -- maybe jumping the gun so to speak -- but was that also mentioned in the Executive Summary? I'm not sure. Is it the feeling of the Panel that Roberts is communicating that outdoor dust is brought in on shoes and so forth, and then becomes a source for residents to ingest this material at fairly high levels.

Is that a really -- I just wanted to ask the question. Is that a really fairly significant source of BaP? That's the first question.

If it is, should it be mentioned just in the summary, just a line?

DR. DENTON: Dr. Pitts, according to Dr. Roberts, it can be in the parts per million range.

CHAIRMAN PITTS: Yeah.

DR. DENTON: And, yes, it would be a significant source, especially for children who are down crawling around on the carpet and so forth.

And, no, it's not in the Executive Summary, but we could certainly add it in.

CHAIRMAN PITTS: Could you add just a line, then, because I think it's important.

All right. Let's see now, we've gone through A, B, and C.

Should we go through the Executive Summary now? Okay. Dr. Becker, do you want to start with whatever comments you have on the --

DR. BECKER: No. They've incorporated the ones that I had stated before. I like the idea that you stated about the uncertainty of the absorption of BaP and included it in there.

And I thought that by adding the uncertainty, they really helped us. I think our other documents would have been helped by adding that statement. That's a good thing to do, and we should encourage that.

CHAIRMAN PITTS: Fine. Dr. Witschi?

DR. WITSCHI: No, I have no comments.

CHAIRMAN PITTS: Dr. Glantz?

DR. GLANTZ: I'm happy.

CHAIRMAN PITTS: You heard that. That's for the record now.

Dr. Friedman?

DR. FRIEDMAN: I'm happy, too.

CHAIRMAN PITTS: Dr. Seiber?

DR. SEIBER: I'd just add one -- I'm happy with it, also, but I had one question. On page 6, "Is there Evidence of Indoor Air Exposure to Benzo[a]pyrene?" in the

middle, the first paragraph, it says, "Woodburning also raises benzo[a]pyrene levels indoors."

And I found the discussion back in the appendix to kind of waffle between, you know, the newer models, which apparently didn't raise it, and some of the older ones, which had a tremendous elevation.

So, I didn't really think that sentence adequately captured that wide range in variation.

DR. DENTON: Dr. Seiber, we can add more clarifying language to this.

DR. SEIBER: Maybe we could say, "From no increase with the latest models, operated according to standards, to large increases. . ." or maybe even put some numbers in there -- "for some of the older models.

DR. DENTON: Will do.

CHAIRMAN PITTS: Fine. Dr. Froines?

DR. FROINES: Probably should be that specific language so we don't get into the problem of --

DR. SEIBER: Shouldn't be that specific?

DR. FROINES: No, should be.

DR. SEIBER: Oh, should be.

DR. FROINES: And if they take that specific language, then we don't have to go back and relook at it.

DR. SEIBER: Well, should we suggest --

MS. SHIROMA: We'll be sure.

DR. SEIBER: Maybe you can give us some suggested language, and we'll all agree to it then.

MS. SHIROMA: Right.

DR. DENTON: Dr. Seiber, Peggy was just telling me that even the newest stoves that they looked at, the homes that have these newest stoves, did have slightly elevated levels of BaP. So, all of these wood stoves, you'd expect to see some increase in the ambient concentration indoors.

DR. SEIBER: Well, I don't know whether anyone else had a question on that particular statement, the statement that woodburning also raises benzo[a]pyrene levels indoors. I don't know whether there's anyplace else in the Executive Summary that dealt with that. If there is, it may be taken care of. But, if not, I think I would just add to that, the elevation being -- varying between small increases or the newer versions to fairly large, you know, be qualitative, or you could put some numbers in.

I think it's kind of an important issue, because people are trying to do the right thing with these woodburning stoves. And you can't really get it from just one sentence here.

DR. DENTON: Yes, Dr. Seiber. We'll add that language.

CHAIRMAN PITTS: And it would be direct from the woodburning stove that's actually inside; but the indirect,

where you transport outdoor air, where the levels drop because of the catalyst and so forth.

I think that's a very good point.

Then I have a couple, just a couple of brief comments. On page 4, at the bottom of the page, it says, "Mobile sources contribute more than 35 percent to the total benzo[a]pyrene. . ." Now, isn't that primarily heavy-duty diesel vehicles? Couldn't you give a breakdown? And I think we should be specific there. Break it down, you know, attempt to be, you know, 10 percent from light-duty, whatever -- whatever that number might be.

MS. SHIROMA: We can do that.

CHAIRMAN PITTS: And again on page 5, we again use the term -- I think when you say "vehicles," on page 5, when you say -- in the second paragraph, fourth line down, "Most vehicles manufactured," you might want to go through and just put light-duty, if you're talking about light-duty motor vehicles. But make a distinction generally. Go back and make a distinction between light-duty and heavy-duty and precatalyst and post. Okay?

DR. DENTON: Okay.

CHAIRMAN PITTS: And I had a question or two on are there elevated levels, on page 6, top. "Are there elevated exposures near sources of benzo[a]pyrene?"

And in the sources there, I think in another part

of the document I saw comments about street canyons adjacent to freeways and roadways, you know, if you're in a parking garage where there's major -- major numbers of diesel-equipped engines -- generally heavy-duty, or light- or heavy-duty, it seems to me you'd want to add some more elevated or other possible source.

Certainly the canyons, the road canyons in private roadways and that sort of thing. Freeways, where you have heavy use by heavy-duty diesels. Or is that discussed elsewhere in the summary?

DR. DENTON: Dr. Pitts, this came from the Quincy-Mammoth study that we had done. And, so, this basically reflects what our discussion was for the near-source exposures of BaP as far as the near-source exposures.

CHAIRMAN PITTS: Okay. Well, then, you might say that -- make that caveat -- put that caveat in, "on the basis of this study on rural regions."

DR. DENTON: Right.

CHAIRMAN PITTS: Whereas, in urban areas, you know, at least discuss in urban regions -- city canyons, you know, by freeways -- heavily used freeways and so forth; adjacent to those, you have high levels of exposure, relatively high levels.

And, then, on page 7, "Are there noninhalation routes of exposure to benzo[a]pyrene?" Maybe, George, you

might want to put in there the dust. That might be a logical place to put in the transport of the dust.

And, then, on page 7, at the bottom of the page, "Nitro derivatives of BaP, such as nitropyrenes. . ." Whoops! "Nitro derivatives of BaP," I think you mean -- you mean nitro PAH?

DR. ALEXEEFF: Yeah.

CHAIRMAN PITTS: Although it's also true -- it's also true with PAH. And, then, ". . .can be much more mutagenic" -- I think, as you do on the next page, you point out the distinction between a promutagen and a direct mutagen. But when you use the term "much more mutagenic," you want to be sure -- you perhaps want to revise that sentence to say, "Nitro derivatives of PAH are direct as well as promutagens, and their direct activities may be far greater than the activities of promutagenic activities.

BaP, of course, has no direct mutagenicity. But you did it on the next page, so it's not a big deal.

But then, finally, there's a question I just ran across. Looking at Table I on page 11, this is an old problem. I'd like to philosophically bring this up with the Panel members and with you folks on this question. We have the two columns. One is microgram per cubic meter and one is parts per billion volume, the unit risk. And, clearly -- or generally -- when we come to airborne particulates,

particular matter, then it's micrograms per cubic meter.

And conventionally, although it goes both ways, if it's a gaseous toxic -- vinyl chloride, either it's micrograms or cubic meter, or parts per billion.

I happen to be a ppb man for several reasons. But, also, I'm wondering whether, just as a question before we get -- well, let me ask my question later.

I think that in the lineup -- regardless of how you look at it -- in the lineup of risk, as you decrease the risk, I think as you get into formaldehyde and perchloroethylene, I wouldn't argue at any moment that the difference between 5.9 and 6.0 as meaningful in any significant manner. But at least, if someone reads this who's not well-versed on 6.0 to above formaldehyde, that's, as I said -- as I said, I think that doesn't matter whether, you know --- given the error bars we put on these things, but at least if someone with the green eyeshade looks over this --- and I think we have a similar situation under ppb, where you have ethylene oxide here, ethylene oxide and vinyl chloride. Vinyl chloride is 2 times 10 to the minus 4, and ethylene oxide is 1.6. I see a 2.6 times 10 to the minus 4 down here for carbon tet. And I see a 5. I'm not sure those are in order of decreasing -- I think they're decreasing micrograms per cubic meter.

DR. DENTON: That's correct.

CHAIRMAN PITTS: But then you need two columns.

DR. DENTON: Right.

CHAIRMAN PITTS: Then you need another column.

DR. DENTON: Another column.

DR. GLANTZ: They don't need to do that.

CHAIRMAN PITTS: Then maybe put an asterisk. Just put an asterisk down and say that this list is --

DR. DENTON: Oh, okay. A footnote.

CHAIRMAN PITTS: Because if I pick up the list and I go down one of the columns, what's he talking about?

DR. DENTON: Right. You're not even sure.

CHAIRMAN PITTS: Now, let me ask another question. If you're going to -- I'm going to talk to the medical -- toxicology/medical people here from the viewpoint of a gas phase -- the gas phase systems, where you talk in terms of ppb, that's talking molecule for molecule. Sort of like Molecule E, like mano y mano. Molecule y molecule in terms of toxicity. Like my Spanish there?

Anyway, you're talking about impacts of two molecules on a molecular basis.

Now, when you talk about micrograms per cubic meter -- in the gas phase, that doesn't relate to this. It isn't a molecule to molecule. It's a weight to weight.

You're sort of letting the old La Voisier and some of these principles -- so, I'm just curious as to what --

whether it wouldn't be a bad idea to put the gas phase in ppbs and put the particulate matter in micrograms per cubic meter. This is from a -- sort of a toxicological/chemical point of view.

DR. BECKER: Well, these are all just put in some sort of rough ranking order anyway.

CHAIRMAN PITTS: Oh, I realize that. I'm just curious. I'm asking this as a general question, because I think, when you talk about it with physicians and medical researchers, do you talk about these things -- think about them as ppb or do you think about them as micrograms per cubic meter in terms of toxicology and their impact?

DR. BECKER: Well, depends on whether there's an internal marker of dose. In fact, if it's a dose in the air, it's much more useful if you had micrograms per cubic meter.

CHAIRMAN PITTS: The gases are micrograms per cubic meter.

DR. BECKER: No. I'd be thinking ppb when it's a gas.

CHAIRMAN PITTS: Well, in the interest of -- in the interest of completing this -- the tasks assigned around the subject, maybe we'll consider it over a cup of coffee. That may be a point. I've had it raised before by students, you know, and I was just curious to see what your thinking

is.

DR. SEIBER: I won't defend it one way or the other, but it's always been explained to me by my toxicology friends that they like to think in terms of amount or unit weight dose per organism. And they're much -- much more familiar with the microgram, nanogram, you know, moving that over to toxicological terms. I don't know whether the rest of you agree with that, but that's the way it was explained to me.

DR. BECKER: You're right.

DR. FROINES: I always use microgram per cubic meter, except when I'm trying to explain this kind of thing to a lay audience, then I use ppbs, because people understand ppbs because they hear it in the press and all of the lay literature more.

So, it's important to me, as a scientist, to use it in the scientific context, the micrograms. But in a public forum, it's ppbs. It's easier for people.

CHAIRMAN PITTS: Okay. Thanks. I appreciate those comments from the Panel. I'm with you.

Okay. Let's see. Where are we now? We've gone through the -- gone through the -- now, we are left with the question of the findings. And we have draft findings here that have been prepared. A question: Would you want to take some time to read through these? It seems to me --

would it be appropriate? Would you want to break now, or did you want to discuss some other subject, or should we take 10 minutes and read these, or more? Because these are the key findings.

DR. FRIEDMAN: I feel we need to read them before we can --

CHAIRMAN PITTS: Absolutely.

Well, what's the mood of the Panel? Do you want to take a ten-minute break or more to look at these, or do you want to --

DR. GLANTZ: Yeah.

CHAIRMAN PITTS: Do you want to go on to Item 2 and break?

DR. GLANTZ: Let's finish BaP.

CHAIRMAN PITTS: I'd like to finish BaP myself. Well, then, let's take a break, and let's come, say, at 10 after 11:00. Yes, Joan?

DR. DENTON: Dr. Pitts, I wanted to mention that in the copy that you were just delivered, on page 4, on Finding No. 17 -- I'm sorry, page 5, Finding No. 17, you'll see that there are symbols after these inhalation unit risk numbers, and those symbols micrograms per cubic meter.

CHAIRMAN PITTS: They are? Now, I know why I like ppb.

DR. DENTON: Actually, it's the font. When you go

in and print up, you have to tell the computer the font that you want. It's also on page 9.

DR. ALEXEEFF: Okay. So, @1\g is --

DR. DENTON: Micrograms per cubic meter.

DR. GLANTZ: So, the thing in parentheses should be parenthesis, microgram per cubic meter, close parenthesis, to the minus 1.

DR. DENTON: That's right. That's right.

DR. GLANTZ: I'm impressed that you can decipher this with all this --

DR. DENTON: Well, we're familiar with our computer system, which tells us -- give us these symbols if we don't print it out with the right command.

CHAIRMAN PITTS: Table 3?

DR. DENTON: Let's see. The last table, Table 3, you can see the unit risk number, it should be micrograms per cubic meter.

CHAIRMAN PITTS: Just the same problem there. Okay. That's -- we can backtrack on that.

Let's take a break then, and we'll read through it and come back at 10 after 11:00.

DR. GLANTZ: Do we accept the report, or do we wait until after the findings?

CHAIRMAN PITTS: Well, I'd like to accept the report, because the findings are based upon an accepted

report.

I'd accept a motion.

DR. GLANTZ: Then, I'd like to move that we accept the report ass revised.

CHAIRMAN PITTS: Is there a second?

DR. WITSCHI: I second the motion with the few little corrections.

CHAIRMAN PITTS: Right. As revised, that's correct.

(Thereupon, several members of the Panel spoke simultaneously.)

DR. GLANTZ: The motion is to accept the report, contingent on making the minor corrections that have been pointed out.

DR. SEIBER: Does that mean that we're not going to read it?

CHAIRMAN PITTS: No.

DR. GLANTZ: No, the report, not the findings.

CHAIRMAN PITTS: We would base our findings upon an approved report. That was Stan's point of order.

DR. GLANTZ: That's correct.

CHAIRMAN PITTS: And the second. We have a second. Any discussion?

All those in favor?

(Ayes.)

Opposed?

(There were no negative oral votes.)

CHAIRMAN PITTS: And another one, so to speak, bit the dust, as it were.

MS. SHIROMA: Thank you.

CHAIRMAN PITTS: BaP. Okay, thank you very much. I'd share the comments of the Panel members. You've done a fine job here in revising this. This is a first-class job, and we all appreciate your efforts.

DR. FROINES: Under our current new guidelines, we now do not present this to the ARB.

MS. SHIROMA: That's right. What we'll do is we'll make these few additional revisions that you've outlined for us today. And if you would like us to provide this to the full Panel or a subcommittee for approval, whichever way you like. And, then, once approved, we'll incorporate all of those changes, print up a clean copy, and then distribute that final copy to our mailing list as an informational item. Then, it's done.

And we would include your findings as well in that report.

CHAIRMAN PITTS: Okay. I'm going to reconvene in 10 minutes.

(Thereupon, a brief recess was taken

for the Panel to read the findings

thoroughly.)

CHAIRMAN PITTS: Shall we reconvene?

All right. We're ready to reconvene and to discuss the findings of the Panel on BaP. These are the findings that we saw some days ago that you sent to me?

DR. DENTON: That's right, Dr. Pitts.

CHAIRMAN PITTS: Basically. So, we have had a chance to look at these in some detail. And I'd now to go around the Panel and ask for any questions or comments on these.

Gary, Dr. Friedman, would you like to begin?

DR. FRIEDMAN: I have a question about Point No. 11 and 13. It refers to the best value for unit cancer risk. And the reason I'm concerned about that is that we already had some discussion today about how much value there's been in the added discussions of uncertainty that we've seen in this report. And I think we're going to be talking about the committee that reviewed the EPA report, and how they stressed how important some discussion of uncertainty is.

So, I don't know -- I think it would at least be good that, when you talk about the best value, to say how best in what sense. How is that -- I don't see any definition of what the best value is. Is it the upper 95 percent confidence limit or something, or what is it?

All I can see here is the best value. And I would like to see some more description of what that is and perhaps, you know, why it's the best.

CHAIRMAN PITTS: Dr. Alexeeff, do you have a comment?

DR. ALEXEEFF: Yeah. The best value is OEHHA's best value. And the idea, you know, stemmed back from years ago where we only reported the range. And there was also some request to provide a single value within that range, particularly if it wasn't the highest value that would be selected for use in risk assessment.

So, in this case, what we're saying is that there are essentially two studies that defined the range, and we think that the lower risk study is the stronger study to use for risk assessment.

We could provide, you know, another sentence or two. But that's basically the source of where best value comes. It's just, from our judgment, the strongest scientific study in this case, which happens to be the hamster study, which, in itself, has some quality problems that Dr. Witschi was pointing out at the last meeting.

DR. FRIEDMAN: Well, I would feel better if it did say that this is the best, and it came from the better quality of the two studies. And what, you know, what value is it? Are you using the upper 95 percent confidence level?

DR. ALEXEEFF: Yes.

DR. FRIEDMAN: I'd like to see that statement there, too. Just to call this the best value without saying what it is or why it's the best seems to be a little bit incomplete. I feel uncomfortable with it.

DR. ALEXEEFF: Okay.

CHAIRMAN PITTS: And maybe you might want to put quotation marks around that, too.

DR. GLANTZ: Nah.

CHAIRMAN PITTS: In addition to what Friedman said.

DR. FRIEDMAN: I don't care one way or the other about the quotation marks. Should you use the term "is estimated to be" instead of "is"? "Is estimated to be"?

DR. GLANTZ: Nah, that's obvious.

DR. ALEXEEFF: The previous sentence states it's estimated to be.

DR. FRIEDMAN: Okay. Fine.

CHAIRMAN PITTS: So, then, you will add the additions suggested by Dr. Friedman.

DR. ALEXEEFF: Right.

MS. SHIROMA: Dr. Pitts, how do you want to handle this? All the times that we go through the findings, we discuss the exact language that you want in your findings.

CHAIRMAN PITTS: That's right.

MS. SHIROMA: And, so, do you want George to work on that and, then, before we wrap up, give some suggested language for you to approve?

DR. GLANTZ: Yes.

CHAIRMAN PITTS: Yes.

MS. SHIROMA: Okay.

DR. GLANTZ: And what I'd suggest that we do, is based on the discussion, maybe, George, you could edit this a little bit. And there's a Xerox machine in the back. And you can hand out a neatly edited version and, then, we can look that over so that we're finished on it today, rather than have us try to write the words, the exact words by committee.

DR. FROINES: Do we -- just a question. I don't want to prolong this at all. When you have a number that's 1.1 versus 3.3 times 10 to the minus 3, do we need a best value? I mean, it seems to me that those are different by a factor of 3.

DR. ALEXEEFF: What we've found in the past is that, unless we selected the best value, then, you know, most risk managers would choose 3.3 in their calculations. So, that's why we're stating that.

They wouldn't run it through with both calculations and do a more complicated analysis. They'd choose one and make some calculation, make a decision, and

then move on.

DR. FROINES: Judging from the newspaper article and the letter Jim Pitts sent us, I was not clear that that would be the choice they would make.

DR. ALEXEEFF: Right. That could be.

CHAIRMAN PITTS: Any comments? Is that it for you, Dr. Froines?

DR. FROINES: No comments.

CHAIRMAN PITTS: Dr. Seiber?

DR. SEIBER: Yeah, I had a comment on Item 3. It says, "Benzo[a]pyrene is a product of incomplete combustion and its major sources in California are agricultural burning, mobile sources," and so on. So, I had the same comment there. I'd prefer to see "open burning of vegetative material." Later on, in Section 4, you mention agricultural waste, and that was quite appropriate, because that's where the study was done.

I think for a more general statement, I would propose that we say, "are open burning of vegetative material, mobile sources," et cetera.

DR. DENTON: Dr. Seiber, that's an "ouch." We changed all of those in the Part A, but it wasn't changed in the findings. But we'll be consistent with what we did in the Executive Summary and in Part A..

DR. SEIBER: And, then, again, back over to 13.

And this is just more an editorial comment. It says, there could be .6 to -- what is it? -- .6 potential cancer cases per million. And I'm not sure that -- when I read that, it says, well, this is really a trivial -- you know, that's not even 1 in a million. That's pretty small.

But I think there are some people who are exposed to higher levels for which there is a significance. You know, in some populations, the rate is considerably higher. I'm just a little bit worried that somebody will read this whole document and come to No. 13 and say, "Why did they even bother?"

Does that bother anyone else?

DR. FRIEDMAN: Well, it bothered me. Why did they bother for such a trivial risk? I have that same question.

DR. SEIBER: I mean, how do we capture the fact that some people are exposed at much higher levels and have a higher rate? Shouldn't that be in there somewhere?

DR. DENTON: Dr. Seiber, you're correct. We have always thought that BaP is not that significant as far as ambient concentrations. It is a hot spot problem. And we're looking for when we put in the --

MS. SHIROMA: No. 4 on page 2.

DR. GLANTZ: I think No. 4 deals with the exposure. But I think it would probably be better to add something, just another sentence to No. 13, saying that

there could be -- the risk to individuals located around hot spots would be significantly higher.

CHAIRMAN PITTS: Exactly.

DR. GLANTZ: Because of the higher concentrations. In fact, you could be it would be 2 to 17 times higher.

DR. FRIEDMAN: I don't know that you can extrapolate -- you know, you can just transfer the concentration to the risk.

DR. GLANTZ: Well, that's the unit. That's the assumption they're making when they're making the unit risk.

DR. FRIEDMAN: People are always sitting at the hot spot breathing it 24 hours a day, not going to work and stuff?

DR. GLANTZ: Yeah, that's true. That's right. I wouldn't put the 2 to 17 in. I would just say, "could be substantially higher."

DR. SEIBER: That was the only comments I had.

DR. FROINES: That, of course, goes back to the issue that I think Jim and I have had, at least all the way through this, is that, when you look at benzo[a]pyrene, this looks de minimis. And, then, we're going to come out with a document that -- with diesel exhaust that shows 3,000 cancers a year. And we're all going to wonder what the hell we're talking about when we do it. I think it's a problem.

DR. BECKER: That's a problem that we've had all

along when we've had mixtures of things. And once again, we haven't dealt with that. And that might be an important consideration when we start talking about an absent number for regulation.

MS. SHIROMA: Also, what we know is that, from the OEHHA analysis, that the potency for BaP is quite high, 10 to the minus 3. But the ambient exposure is relatively low, because the X does not hang around a long a time. What's the half life? About 10 hours?

MR. KRICHEVSKY: Yes.

MS. SHIROMA: Thereabouts? Yeah. What we know is that it's very potent. But from an overall ubiquitous ambient risk, it's low. Meanwhile, we can add that sentence to No. 13. Joan, you want to read that sentence?

DR. DENTON: "Risks" -- this is the last sentence to No. 13. "Risks to individuals around hot spots could be substantially higher."

Dr. Glantz, did you want us to remove the 2 to 17 times higher in --

DR. GLANTZ: No.

DR. DENTON: -- No. 4, or just --

DR. GLANTZ: That's fine.

I have a number of things. In No. 7, where you're talking about tobacco smoking, you had some numbers in the report about how much it raised the indoor levels and that

you would end up with higher levels indoors than outdoors. And I'd like you to put those numbers in the findings.

MS. SHIROMA: All right.

DR. GLANTZ: They were in the report. I just don't remember what they were.

And, then, in No. 12, you say, "The range of risk values results from several sources of uncertainty, including statistical uncertainty."

What "statistical uncertainty"?

DR. FROINES: Can I ask you a question --

DR. GLANTZ: Yeah.

DR. FROINES: -- Stan? I think 12 -- now that you mention it -- George just said it's based -- the uncertainty is based on two different experiments, and none of this is relevant as far as compared -- in terms of what George said.

DR. ALEXEEFF: Are you talking about 12?

DR. FROINES: "The range of risk value results from several sources of uncertainty, including" blah, blah, blah, blah, blah. But, in fact, what you said is that there were two studies with two different risk estimates, and that was the range. Is that right? Am I wrong?

DR. ALEXEEFF: Yeah, right. I guess what this is saying is that the -- it's probably more precise to say the values within the range of risk, the ranges of risk have these sources of uncertainty inherent in them as opposed to

these are causing --

MS. SHIROMA: Right.

DR. ALEXEEFF: -- the range.

MS. SHIROMA: The semantics were --

DR. FROINES: Yeah.

MS. SHIROMA: -- turned around on this.

DR. GLANTZ: I think that's an important change, because the way I read this was what George just said, which you're right, it isn't what it says.

I would say something like "The estimate of risk includes several sources of uncertainty," or "is affected by several sources of uncertainty."

And I think all the other things are fine. But I don't know what the statistical uncertainty is..

DR. FRIEDMAN: Well, I feel uncomfortable trying to answer a question about statistics to you, but isn't it just sampling variation?

DR. GLANTZ: Yeah. I mean I thought statistics was about uncertainty. I mean, if there's no certainty, then you don't have a statistical problem.

(Laughter.)

DR. GLANTZ: I mean, I don't want to sound like a professor or anything. There's no such thing as statistical certainty.

DR. SEIBER: Well, I would have read it -- just

taking it on face value, that means the choice of a statistical operation where there's maybe three different ways to analyze the data, and you've chosen one out of the three. That's the way I read it.

DR. GLANTZ: Well, what did you mean? I see a lot of smirking out there.

For the record, the staff is smirking.

(Laughter.)

DR. ALEXEEFF: Well, I guess, as Dr. Seiber was pointing out, it refers to the uncertainty in the statistical approach that's used in this.

DR. GLANTZ: Then, you should say, "including the mathematical model used to estimate the risk," or "the choice of the mathematical model used to estimate the risk," or something like that.

And, then, after No. 13, I think it would be -- when you talk about the potential cancer cases, you're talking there about the outdoor exposure. Can you say anything about the indoor exposures? Because you made a good case in the report that there is often significant indoor exposures that are higher than the outdoor exposures, either because of cigarette smoke or wood stoves, things like that.

Can you add a sentence to that to say the indoor exposures would add between so many and so many potential

cancers?

DR. DENTON: We have that information in the Executive Summary, which we could add.

DR. GLANTZ: Yeah. I'd like to see that.

And on behalf of our esteemed Chair, in Table 1, you should move formaldehyde up to keep things in order, because of the compelling argument made earlier.

But, other than that, I'm fine.

DR. WITSCHI: Yeah, I have a -- point 9. I couldn't rewrite right now, but I think it should be made clear that what you -- the studies you cite here makes us think benzo[a]pyrene could be a human carcinogen, but we don't know by no means. It's part of the mixture. So, I would be a bit more careful.

And, then, what are patent fuel workers? And, then, the other one -- where did the creosote-exposed brickmakers come from?

CHAIRMAN PITTS: Aren't those attorneys?

DR. WITSCHI: What about coke oven workers? That's what it usually is associated with, coke oven workers.

DR. FROINES: I don't think they use creosote anymore, because you can't use it anymore. It's a toxic.

DR. ALEXEEFF: That came from the IARC document.

DR. WITSCHI: What's a patent fuel worker?

DR. BECKER: IARC really concludes that the data is inadequate here. So, if it comes from that, it's inadequate. So, you might want to -- that was one of my comments.

DR. GLANTZ: Would we be better off just deleting No. 9, since no one here seems to know what a patent fuel worker is?

DR. ALEXEEFF: I think what would be useful is -- I can try to rewrite it right now and respond to the change that made to the text.

DR. WITSCHI: Well, I think it can stay in, because that's really all the evidence we have.

CHAIRMAN PITTS: Why don't we add -- I agree with you, Hans -- epidemiological evidence of human cancer from exposure of benzo[a]pyrene in complex mixtures.

DR. WITSCHI: Yeah.

CHAIRMAN PITTS: And drop it off -- we can't define patent fuel workers, leave that out.

DR. FROINES: Could I ask a question then? If you're going to include coke oven workers, you should also include diesel exhaust if you're going to make a list of these things.

DR. WITSCHI: The point you really want to make in this one is that it's one of the most best known carcinogens in animals; the evidence that it's a human carcinogen is

really only circumstantial, because it comes only from mixtures that -- I think that point needs to be made.

DR. ALEXEEFF: What I thought we could do is take a sentence from the section which was changed, you know, today, about several mixtures containing PAHs are carcinogenic to humans. And then we can add what you were just indicating -- "although benzo[a]pyrene itself has not been implicated in the human studies."

DR. WITSCHI: I would agree.

Okay. On page 5, 18, "below which no carcinogenic effects," wouldn't it be better to say "carcinogenic risks are anticipated"?

I think there's a difference between risk and effect, you know.

DR. FRIEDMAN: Why don't you like effect?

DR. WITSCHI: Well, there's plenty of evidence that there's a level where you do not have any carcinogenic effects of benzo[a]pyrene. You have a "risk," but you do not have an "effect." And I think it's an important distinction.

DR. FRIEDMAN: Well, if there's no effect, then there's no risk.

DR. WITSCHI: No, the risk is so much more abstract. You know, it's always a possibility. But you never can -- you can infer there is a risk. You never can

demonstrate there's going to be an effect.

DR. FROINES: You're dealing with probablistic risk assessment.

DR. WITSCHI: Yes.

DR. FRIEDMAN: I mean, you can actually show that below a certain level that, you know, there's no chance that there would be any carcinogenic effect? Because that goes against every report we've put out here.

DR. WITSCHI: Well, to me, an effect is something that you can see. A risk is something I can live with as a possibility. An effect is really something I can see.

As a matter of fact, every carcinogenesis study in animals has a level most of the time where you do not see any effect for different reasons. Maybe it's a question of words, you know, but --

DR. ALEXEEFF: Yeah. Maybe we can change it to say "below which no effects related to carcinogenicity," instead of -- because, for example, we have the DNA adduct information where we don't have statistical increases of cancer rates. So, there's information around potential carcinogenicity, although it doesn't actually show statistical increases.

DR. FROINES: Let me make a suggestion, because the law requires us to make a finding -- this is what happens when you've been on the Panel so long.

The law requires us to make a finding of whether a threshold exists. The finding we should make is that we were not able to determine a threshold and forget all this other stuff.

CHAIRMAN PITTS: That's right. Dr. Becker?

DR. BECKER: Most of my comments were covered. I did think that the letter was pretty convincing about the dust, so I thought you might want to add to No.7 about the dust.

Under 9, while IARC concludes it's inadequate -- for instance, I think I'd split up No. 9, basically, and say that since the 1700s, people have suspected that benzo[a]pyrene caused lung cancer in chimney sweeps, but data has not been adequate, although suggested by these other things. Doesn't that make sense? Because I think the epidemiology, while uncertain, it's sort of reasonable to make that comment about it, especially with the mineral oils, for instance.

There is substantial evidence about inks that contain carbon black, for instance. Those data are a little more impressive than some of the others. Actually, they've taken the hydrogenated oils that go into the inks -- they actually took it out in the mid-1980s on the basis of the epidemiology.

My only other comment was in No. 8, which actually

is covered later. We talked about this once before, and that is that there is exposure from these other sites, but the percent of absorption is unknown. So, it's very hard to know -- to make the doses there. You corrected that in the document. It might be worthwhile adding it under No. 8.

DR. ALEXEEFF: You mean change exposure to dose?

DR. BECKER: Right.

Mr. Chairman, you have a lot of things to comment on, right?

CHAIRMAN PITTS: Pardon?

DR. BECKER: You have a lot of comments, right?

CHAIRMAN PITTS: Oh, a couple. I was just reviewing the comments to shorten them and toss a little out.

On 1, you might add in the first line, "particulate polycyclic organic matter," and then put in parentheses, "POM" after that.

And, then, I didn't see in here a statement regarding the fact that BaP is present in the submicron particles and is combusted generated and is generally found in submicron respirable particles. That's kind of an important aspect. So, I thought maybe we could change -- let's see if we could change 3, the first sentence of 3 -- and, John, see if I'm getting this correct.

"Benzo[a]pyrene is a product of incomplete

combustion; it is present on the surface of the associated emissions of submicron respirable particles on the surface."

Now, actually, what you do to measure the benzo[a]pyrene on a particle you extracted with an organic solvent, so, really, it's another term -- it's extractable by organic solvents. You might want to modify -- I think it's important that we note the submicron and respirable, and that it's extractable from the surface.

And, then, on 5, "Before the introduction of the catalytic converter, mobile sources. . ." that can be okay there. That's a general statement. But I would have said, "mobile sources with spark-ignition and diesel engines" were the major contributors. Because you've got two types of engines. And I'm referring to light-duty in this case.

"After 1974, in California," vehicles were operated.

And then we come down to "Reductions in BaP emissions. . ." by the way, why don't you just use BaP throughout after you've defined benzo[a]pyrene, you can shorten the whole thing by just putting BaP in it.

"Reductions in BaP emissions are also expected as a result of decreases in respirable POM." Put "respirable" again in there. And then, at the end of the sentence, "low-emission vehicles and clean fuels." Now, here's where I would like quotes around "clean" fuels, Quote, "clean,"

unquote, fuel.

And, then, I would add a sentence there, if I'm correct in this, "Respirable particulate matter (soot) from light- and heavy-duty diesel-powered vehicles continues to be a significant source of BaP emissions."

Am I right, John? That statement, I believe, is correct. Didn't say "major," but a "significant" source.

And, then, in -- I'm not going to worry about that.

And there's a point here on 6. We're talking about the lifetime of benzo[a]pyrene on page 3. Could we add a sentence, then, when we're talking about chemical reactions -- which is a fairly short lifetime in the atmosphere. How about a sentence like this: "Relatively little is known about the carcinogenicity, or lack thereof, of the reaction products. We know very little -- in other words, you have transformations. You're forming a variety of products, and very little is known about the health effects or lack thereof of the products. And, then, I added a little -- another statement and a comma, "an area warranting expanded exposure and health effects studies."

And that fits with the idea we form all the nitropyrenes, the oxy compounds, the lactones. Nothing's really known about them. So, keep thinking about that.

I think that's basically all I have to comment on

this. Are there any other comments? Now, would you like to see these findings then come back? I would prefer that myself.

All right. If you would do that.

MS. SHIROMA: I'm sorry. I just wanted to make sure that I understood your instructions.

CHAIRMAN PITTS: My instructions are that you'll go ahead and make these additions and modifications, and then bring them back to us clean copies of the modified comments. And, at that time, we'll review them again and, then, make a decision on it.

MS. SHIROMA: Okay.

CHAIRMAN PITTS: Now, while we're on Item 6, going back to a motion that was made in the previous meeting -- Dr. Seiber made a suggestion related to all of this, and he now has a formal statement of that motion that I'd like to introduce.

As a matter of fact, while you're still up here, stay with us here -- stay tuned. I'd like Dr. Seiber to read his motion that we had brought up in February.

DR. SEIBER: When we went through the discussion with BaP -- and I think it'll come up in additional discussions of mixtures, and particularly mixtures emitted from incomplete combustion. There seems to be a lot of questions and unknowns. And it's going to be hard for SRP

or any single entity to sit through that information and make findings without plugging some of the holes.

So, therefore, the motion -- and I'd like to read it for the record. It's just a draft motion at this point in time, so it needs to be discussed and modified. The motion that we have written so far reads as follows:

The SRP conveys its concerns to ARB that there is insufficient data regarding emission sources and ambient levels in order to conduct thorough risk assessments for products of incomplete combustion, such as PAH and the environmental transportation products.

The SRP requests that -- and I'd like to modify my own writing at this point -- that the ARB -- not ARB Research Division, but ARB -- consider the availability of data and provide funding for research and/or monitoring in order to collect information which is presently insufficient.

Examples include: woodburning (stoves, fireplaces, outdoor timber clearing), wildfires, agricultural burning (orchard prunings, rice stubble, et cetera), roadside weed control, as well as transportation and power generation.

That's the end of the draft.

DR. FRIEDMAN: A point of information. What are environmental transformation products?

DR. SEIBER: This is what Dr. Pitts was referring to as the PAH gets out in the environment and it's photolyzed, what are the products? The secondary products.

DR. FRIEDMAN: So, maybe instead of "the," its, maybe "its" would be a better word there?

"PAH and its environmental" --

(Thereupon, several members of the Panel spoke simultaneously.)

CHAIRMAN PITTS: There's a motion made. Is there a second to the motion? Discussion?

Froines seconds the motion. Discussion?

DR. FROINES: I think one thing, it would be useful to say there's insufficient data regarding emission sources and ambient levels of -- something -- toxic air contaminants, PAHs. Oh, I see. You've got PAHs down below. Okay. Maybe I'm wrong. I'll withdraw it.

DR. BECKER: Jim, have we ever done this before? I think we have. I think we asked one or two times before and I think that makes this appropriate, because I think it's the next -- in addition to the things that are new, at least for me, as a Panel member, doing risk assessments on things other than cancer where thresholds are not the issue; and, secondly, we're now going to complex mixtures as broad topics, which we've never dealt with before.

And there might even be some need for a preamble

that would say we anticipate in the future that we're going to need data on complex mixtures that we need to do better risk assessments. You might want to set that out a little more.

DR. FRIEDMAN: I feel a little uncomfortable making recommendations without knowing what would be sacrificed if they did this kind of research. I mean, they have limited resources. I don't know what research they're doing. Maybe what they're doing is much more important than something which seems to have a relatively low overall cancer burden or risk. So, maybe it would turn out it would have a much higher risk if we knew about these sources, but can we really make this kind of recommendation without knowing what it's competing with?

CHAIRMAN PITTS: Jim?

DR. SEIBER: Well, I don't know the answer to the question. The ARB has a research agenda. I think they have a published document and I haven't actually looked at it recently, so I can't address your question. But it's a legitimate question. If you do more here, it means you can do less somewhere else, and what's the tradeoff?

CHAIRMAN PITTS: I think, though, the phrasing may cover this. The SRP requests that the ARB consider the availability of data.

I don't think we have to worry about -- I think

the ARB will get the point that we think it's important to-- it's an important area and they will fit it into their priorities. Do you want to use the term "explore it as a priority item," perhaps?

MR. BOYD: Yes, Dr. Froines.

DR. FROINES: One of the things that has struck me, since I've been on the Panel -- and I was surprised at when I first joined -- was there's always been the lack of information that we have available on airborne concentrations of toxic air contaminants.

When I first came on the Panel, I thought we knew a great deal about all these chemicals and everybody else did, and it was just me who was missing. And, then, it turned out that it wasn't me; it was that we really don't have as much information as we need on the ambient and hot spot concentrations of toxic air contaminants.

Some of that, presumably, is being addressed in the 2588 process, but even that's not airborne concentrations. It's really more emissions and surrogate ways of making exposure estimates.

And I think PAHs and their atmospheric transformation products is a very, very important issue in California, because, clearly, the formation of nitro-PAHs in the South Coast, issues in the valley in terms of agricultural burning -- and I say that only to contemplate,

Jim, the shorthand way of saying it -- but there are clearly a number of issues. And, so, I certainly can support this. There are now 189 compounds on the Clean Air Act amendment list, and a lot of them, I think, have -- there's absolutely none of it in the ambient environment whatsoever.

And the trouble when you pick up chemicals based on a list, that you end up with a lot of compounds that are totally irrelevant. And one of the questions that we may want to take up at some point, just for information purposes at least, is what is being done to better develop our understanding of the concentrations of toxic air contaminants?

But I think that PAHs, at least in this particular sense, are sufficiently important that I think it's an area of some priority.

MS. SHIROMA: Dr. Pitts?

CHAIRMAN PITTS: Sure.

MS. SHIROMA: So, as I understand, the Panel believes that PAHs and the transformation products are an important area where there is a paucity of data that could have large implications, but we don't have the answers yet.

So, you want ARB to look at resources to measure PAHs and transformation products or to look at -- are resources available for research money to do this. So, as you were discussing, we'd have to take a look at the overall

priority for ARB.

But in the meantime, Joan has spoken with Mike Poore, who is our chief chemist on the opportunity for including additional PAHs in our ambient monitoring system, our 22 station network. Joan, do you want to --

DR. FROINES: Can I just make one comment? As George presents us with PAHs' potency values that we haven't had before, when we then go and say, what are the concentrations in the environment associated with those new potency values we're taking up for the first time, it seems to me that we really -- those new potency values by themselves evidence a need for information. And it may be that we need to look at some of the compounds, especially those that have greater potency than benzo[a]pyrene, for example, as a priority item. So, there may have to be some measure of priority setting as well.

DR. SEIBER: And it was a little more general than PAHs, "such as PAH," so it really was products of incomplete combustion, so it casts a somewhat broader net.

DR. DENTON: I just wanted to mention that, yes, we have talked to Mike Poore several times. And, in fact, following up on your idea, Dr. Froines, about these potency that are going to come across. What we have done is we've arranged with Roger Atkinson and Janet Arey to look at what's available actually in the literature as far as

ambient concentrations of those PAHs for which we now have PEFs, which were developed as a consequence of the benzo[a]pyrene document.

And Dr. Atkinson and Dr. Arey are doing that basically now, and we expect to have some information from them by the end of this month. And, then, at that point, we'll be getting back with Mike Poore and seeing what's exactly feasible as far as ARB's monitoring network.

CHAIRMAN PITTS: That's great. I think the transformation process -- that's really a critical issue. You know, I shot a PAH into the air and it fell to earth I know not where or how, in what form. And the naphthalenes, put naphthalene into ambient smog and you get nitronaphthalene in a matter of a couple of hours.

And these are there, and they constitute -- they contribute to the overall mutagenicity of ambient air that we breathe. You can express the air we breathe in terms of mutagens per cubic meter if you do an Ames test.

And, so, I think this is an important area. It's also important in another respect that's often overlooked. That is, we think of environmental transformation of PAHs, for example, in terms of possible health effects. But you undergo oxidation to form hydroxy compounds. You increase the polarity. You go from a veritably nonpolar PAH to a highly polar species, which dissolves in the water, like

that. Dissolves more readily, more soluble. It adsorbs to surfaces, particles, dust, to soil. It'll dissolve in water droplets. In other words, you fully change the chemistry of this and, therefore, you change the transport through the environment, through the ecosystem. As well as the possibility of having a health impact, you have these other areas.

I've seen risk assessments some years ago that -- for benzo[a]pyrene that had a -- came into a river here, and four days away it goes out down there or something, and they still think it's benzo[a]pyrene. And probably most of it isn't.

And you really need to know what is it coming out. Oh, okay. So, I guess the message is there. This environmental transformation refers not just to -- you might add that, not just in terms of potential cancer impact, but in terms of the impact on the ecosystem, in terms of their increased polarities and associated aspect.

I'm jumping ahead to the National Academy. We have two members of the Panel that prepared this. But I noticed the summary, and it relates exactly, precisely to what you were saying. Exposure assessment -- they say in the summary here in parentheses, "An important component of an exposure assessment is emission characterization, determine the magnitude and properties of the emissions that

result in exposure. This is usually accomplished by measuring and analyzing emissions, but that is not always possible. Therefore, modeling is often used to establish..." But I didn't see in here the transport and transformation formation (sic) and fate in the -- transport transformations are critical to exposure assessment.

I mean, you spray malathion, but the Food & Ag, the Pesticide Division, has shown that you spray malathion, and two days later, you have more malazone (phonetic), which is a toxic, 70 times more toxic malathion. It oxidizes rapidly.

If there are any trout fishermen in the audience here, people who are interested in the upper Sacramento River, remember the metam sodium. That wasn't what nailed the ecosystem. It was the product reacting with water.

So, I think this is sort of a background of what you're saying the need to be of -- and I might add that maybe from a cost-effective point of view, you think maybe more important or less important? It may be something trivial. That's good to know. On the other hand, if there is something there that has a really enhanced toxicity, whether to animals, plants, forest ecosystems, it's important to know that also.

I don't expect you to get all that down, but you've got the idea. You know me well.

All right. Are there any other comments then? If not, then we will then pursue the next item on the agenda. Will that be the risk assessment? Are we leading into that, the risk assessment? Oh, the tobacco smoke. ETS.

DR. SEIBER: Jim, with this motion, we didn't come to an actual vote, I don't believe. It's been modified substantially. What would you like for us to do with that? Have it retyped?

CHAIRMAN PITTS: Why don't we have it retyped and re-presented to the Panel, and we can modify it as we see fit, and then we'll bring that up at the same time -- subsequent to the findings.

Good. Let's move on to the next agenda item. And this will be a discussion of the status of OEHHA Environmental Tobacco Smoke risk assessment.

George, I'll turn it over to you, and you can turn it over to whoever is --

DR. ALEXEEFF: Okay. With me today are Dr. Lauren Zeise of the Reproductive Cancer Assessment Section in OEHHA, and Amy Dunn, and they'll be discussing the current status of the ETS document.

DR. FROINES: Reproductive Cancer?

DR. ALEXEEFF: Reproductive and Cancer Hazard Assessment Section. I left some words out there.

(Thereupon, the reporter requested the

microphones be used.)

DR. ZEISE: Lauren Zeise. OEHHA, in collaboration with the Department of Health Services, is developing health effects and exposure documents on environmental tobacco smoke. We have six documents at various stages. A document on respiratory effects, reproductive and developmental effects, cardiovascular effects, cancer, and cancers other than the lung, lung cancer, and exposure.

In addition to SRP review of all six documents, we will also anticipate the Proposition 65 developmental and reproductive toxicant I.D. committee, which is a committee within the OEHHA Science Advisory Board, we anticipate their review of the reproductive and developmental effects document.

Now, all but one of the six documents are now or have already been through internal review. Documents on respiratory effects, cancers other than the lung, developmental and reproductive effects have been sent to the ARB for review, who also in turn have asked the SRP lead for review of those documents. And we've gotten back comments on those three documents.

OEHHA has sent last week a time line for the anticipated release dates of all the documents to the ARB, and I think that that was shared with the Panel. So, you can see all the time lines that we anticipate releases of

the respiratory effects documents and the document on cancers other than the lung by May 2nd. We anticipate the release of a document on reproductive and developmental effects by August 15th.

That document is also in a parallel process for the SAB DART I.D. committee. And so, that August 15th release date reflects that review process as well.

The document on cardiovascular effects, we anticipate its release by August 15th, exposure assessment by September 1, and on lung cancer, which is an update of the information already available on lung cancers, by September 30th.

So, that's where we stand. If you have any comments or suggestions, we'd be happy to hear them.

CHAIRMAN PITTS: Why would I turn to Dr. Glantz for comments here?

DR. GLANTZ: I don't know. Random. It's statistical variability.

Now, Lauren, did I understand you to say that -- we were just discussing a crucial policy matter up here when you started talking -- what time we were going to go to lunch.

But I said we should put lunch off till midnight, so that we adequately discuss this. No.

But you said that the first four are already well

along or have been drafted and in internal review; is that what you said?

DR. ZEISE: All documents, except the lung cancer document are in or have been through internal review.

DR. GLANTZ: Okay. Well, the --

DR. ZEISE: Nearly through, I should say.

DR. GLANTZ: Okay.

DR. ZEISE: I should have said the initial internal review phase, because some documents have already been all the way through it and have been sent back with comments. So, we are now incorporating and looking at those comments.

DR. GLANTZ: Right. I think, obviously, the first two -- May 2nd is only what, three weeks away. So, that's fine.

There's another kind of externality pressing on this that I think is important. And, as you mentioned, the reproductive chapter was informally looked at by the SRP. And that's a potentially very important document. And OSHA is in the process of a rulemaking on environmental tobacco smoke. Have you seen the OSHA rule?

DR. ZEISE: No, I haven't.

DR. GLANTZ: Well, we'll make a copy of it. It's excellent light reading. But the public comment period -- I think, first of all, you want to get a copy of this, because

there's a lot -- it's got a good review of the literature in it. And the other thing is, I think they would be very informed by the work you've been doing. And the public comment period for the OSHA process closes June 29. And I think it would be -- I think you need to move up the public comment release dates for your August 15th document to get it into OSHA, so they can have the benefit of the work that you've done. Because the quality of work that you people generally produce, as we've said, is quite good. And I think it would really have a tremendous impact on the process well beyond California, even if the only thing that was available was the public review draft, simply because of the thoroughness and the quality of the work you do.

So, I really urge you on the two that are currently in the process, to try to get those out in time to submit them as public comments to OSHA. I think that's less important -- I don't think it's that important at all for the lung cancer. Because, as you said, that's an issue which has been dealt with very thoroughly by the EPA. And I think I don't anticipate that being a major additional document anyway.

The exposure assessment would be nice, but I think, you know, the California ETS exposures are probably going to be a lot different from the rest of the country, because of the success of Proposition 99 and a lot of other

things.

So, it would be nice if those were available, but I think that would really even be pushing it by my standards.

But to get the other two out by the end of June would, I think, be very useful. And I think it would also, by getting it into the OSHA process, that would also have the effect of getting you a lot more feedback on the document in terms of what you would write. And, ultimately, we could do a better California document.

DR. ZEISE: Thank you. I will share that internally with the folks within OEHHA. I don't think we can make a decision here.

DR. GLANTZ: No, I understand. I think that the reproductive one -- I can't believe, given the level of work that's already been done on that, that you couldn't make that one. It'll be nice to see the heart disease one. They have a very nice discussion of heart disease in the OSHA rulemaking, too.

I had one other question. These will be released for public comment on these or some other dates?

DR. ZEISE: These are the dates we anticipate.

DR. GLANTZ: Right. So, let's say, then what will then happen after you release the document on respiratory effects on May 2nd? Could you tell us what will happen

after that? What the process will be?

DR. ZEISE: The process will be very similar to that followed by AB 1807 documents. There will be a public comment period. There'll be a workshop on the documents. Although, I'd anticipate that we'd try to cover a couple documents within one workshop.

There will be the same kind of review and revision of the documents that you see under AB 1807, except we will not have that final public comment review period before the Board.

Now, the developmental and reproductive effects document is a little bit different, in that it will have to go through the Proposition 65 process as well.

CHAIRMAN PITTS: Are there other comments?

DR. BECKER: I've had a chance to review several of these, and they're really quite far along. I guess I'm a little surprised it's taken so long, because the quality of it is really very good, you know. I would just like to encourage you -- I don't know how to say it politely -- but just to speed it up. Because it seems to me there's a lot of -- especially watching those hearings last week -- a lot of enthusiasm and interest on the part of the public to want to know these things.

And it sort of looks like it's after the fact that you're putting this up. So, it seems to me that, at least

the ones that I've read, are of such high quality that they could be -- there's not a lot of work that would be required for it.

DR. ZEISE: The goal is a very high quality scientific document. There's a lot of public interest in this area. And the internal review is extensive. So, what we're trying to do is produce as high quality documents that we can.

DR. BECKER: For instance, the one on cancers other than the lung is was just -- that was a very good document and, really, it needs to get out as soon as possible. That's my point.

DR. GLANTZ: I'd like to just -- Chuck shared those with me, too. I mean, I also have been very impressed with the quality. And it seems that the internal reviews are taking an awful long time on something that's, to me, looked very good to begin with. The reproductive effects thing, most of the criticisms that I was -- were more on the presentation than the content. Again, the science was very well done.

And, so, I realize that this is an area where you have to be very careful, as you should be with everything, but particularly, you're going to have the tobacco companies breathing down your neck.

But once it's right, you know, it's right, and you

should let the thing out and let people comment on it.

So, I'd just again like to reiterate what I said and what Chuck said. I think this is kind of a protracted schedule given where you are and where you already are in those documents. So, I hope you will share that with the people back there.

And, again, getting this out in time for the OSHA people to have the benefit of your work I think is very important. You know, a lot of what we do here has an impact way beyond California. And this is the place where there's going to be a very significant effect.

DR. ZEISE: Thank you.

CHAIRMAN PITTS: Are there other comments by other Panel members?

Gary, do you -- John, do you have comments on this?

DR. FROINES: I'm fine. I agree with Stan. I have a specific thing I'm curious about, which has nothing to do with environmental tobacco smoke, so I was actually looking for that.

I agree with Stan's point of view. I was in Washington last week. And I think that it's good to get it in for the OSHA hearings. I suspect that standard is going to take quite a while. This document does not contain a benefits section, and so they're already in hot water.

So, I think this OSHA standard may be being debated for some time. I think we can probably move faster in California than the Federal OSHA.

DR. GLANTZ: I will be very surprised if the final OSHA rule comes out any time soon. But I still think it would be worth having the benefit of the work done here in California in the pipeline, so that it would at least get looked at.

DR. FROINES: Can we get a copy of that?

CHAIRMAN PITTS: Yes. Bruce Oulrey will be getting copies of that for us.

Why don't you just mail them to us? Do you want the entire document there or just a couple pages?

DR. GLANTZ: The whole document is actually very interesting. It doesn't just deal with environmental tobacco smoke. It deals with the whole range of indoor pollutants. It has a very thorough literature review in it. So, I think it will be helpful to everybody here who's interested in this to take a look at it.

CHAIRMAN PITTS: If you would, Bruce, we'd appreciate it.

Very good. That's fine. Any further discussion on this? Let me ask one quick question. As you go through, in addition to another basically -- what's the word I want to say -- noncontroversial subject, like diesel exhaust,

will you follow more or less the same -- the respiratory effects, cancers of the lung? I'm very interested in that question for several reasons.

Do you follow something along the same pattern, then, will you, with diesel exhaust?

DR. ZEISE: In terms of diesel exhaust -- George, maybe --

(Thereupon, Dr. Zeise turned to Dr. Alexeeff and spoke, which was not heard by the reporter.)

DR. ZEISE: I'm not sure exactly what you need.

CHAIRMAN PITTS: Is the content of the discussion and the timetable you've handed out, I'm just asking all three of you, in general -- because I think it's a very important aspect. We've heard so much about lung cancer being a primary impact of diesel exhaust and what happens -- whether, for example, one uses particles that do not have organics on them versus particles -- other inorganic particles, generate -- generate tumors. My understanding is that maybe refers specifically to lung cancers. And I'm curious as to whether, for example, if you find other particles in conjunction with diesel exhaust studies, do you produce other cancers -- bladder cancers and so forth -- do the runs in the studies' exposure, in which you use the straight inorganic crystalline material, also produce -- in addition to whatever lung tumors one may get -- tumors of

the bladder? This is a major issue. I'm just curious about how that'll be approached.

DR. ALEXEEFF: Well, we will look at it -- I'm sorry. I can't recollect if anything other than lung cancer is associated with diesel exhaust exposure.

But if it is, it certainly is not as pronounced or as evident as with cigarette smoke studies.

CHAIRMAN PITTS: But you will look at that.

(Thereupon, both parties spoke simultaneously.)

CHAIRMAN PITTS: You look at it in context.

DR. ALEXEEFF: Right. So, we're, in part, limited by the studies available -- actually, in great part limited by the studies available.

But we're looking at it to see if any other cancer sites have occurred from diesel exhaust exposure. I just don't recall any others other than lung cancer. But I can't say for sure.

CHAIRMAN PITTS: You will check that, though.

DR. ALEXEEFF: We will.

CHAIRMAN PITTS: Okay. All right. Thanks very much. I think that will handle that.

DR. GLANTZ: Do you know when we're going to get the revised draft findings back so we can look at them?

CHAIRMAN PITTS: Genevieve, how do we stand on those?

MS. SHIROMA: Probably within the next half hour.

CHAIRMAN PITTS: Okay. Fine. Well, let's continue then to the next item, actually the final item on the agenda, other than meeting dates.

Discussion of the National Academy of Sciences' publication, "Science and Judgment in Risk Assessment," prepared by a distinguished group of scientists prepared by the National Research Council, of whom two of the distinguished scientists sit here today on our Panel.

So, it's not clear to me how this discussion was to be focused. Would -- did we have -- actually, either you, Jim or Hanspeter, were you going to speak to -- initiate the discussion on this? If you would, Hanspeter is a member of this Panel and Dr. Seiber's a member of this Panel. And it's a subject of considerable interest at all levels -- the scientific and the regulatory aspects of it are most interesting, and public policy, of course.

So, I'll turn it over to you to initiate the discussion.

DR. WITSCHI: I'll be glad to. I would like to highlight a few things of this report, which I think might be important for this Panel. But, also, being a biologist, I limit my remarks to what I think is important as far as the risk assessments are concerned.

Chapter 2, which is called "Risk Assessment and

its Social and Regulatory Contexts," is really one of the better chapters. It was written by one person, and is extremely lucid, and gives very much the history of risk assessment, how we came to the process and its results through times, really the process of risk assessment and how it evolved over the last 20, 30 years.

It's a great chapter. It's very well written, and I use it extensively for teaching purposes.

Another thing is Chapter 7, "Models, Methods, and Data."

I think what I'd like to particularly call your attention to is page 7-23, which is around 7-23. It's a new scheme of how to classify carcinogens. And without going into details, there are some innovative approaches in how to do this. It somewhat deviates from the old EPA scheme and also from IARC's scheme.

Then, Chapter 9 deals with uncertainty. And without going into much detail, I think this is a very well written chapter, which raises many of the issues, and so does Chapter 10, on variability. And I think, again, all those chapters are very readable.

And, finally, I'd like to call your attention to two appendices, Appendix H-2, which discusses and provides literature on individual susceptibility factors, which is becoming more important; that people are not just inbred and

homogeneous in their reaction, but really might vary.

And probably the most interesting Appendix N-1 and Appendix N-2. Because of this particular issue, the committee was split and could not reach consensus. And the two appendices, N-1 and N-2, really reflect the two schools of thought within the committee on which really agreement wasn't reached.

So, this is what I would say are the most readable things in this report. And I think, Jim, you might have to add some other things.

DR. SEIBER: Well, again, I'll speak from my perspective, as one of the chemical exposure people on the committee. It was a large committee, by the way. You can see the names on the front, I think 20 or so members of the committee, often referred to as the CAPRAH (phonetic) report. You'll see that name. I think that's a rearrangement of the words "Committee for Assessing Risk Assessment from Hazardous Air Pollutants," but it's pronounced CAPRAH.

One particularly interesting conclusion and recommendation from my point of view is actually found in the top of the Executive Summary, E-10.

It says, "EPA should screen the 189 chemicals, that's the HAPS, to establish priorities." And I think the reason for that recommendation is that the committee saw EPA

with this large list of chemicals, and we wondered how they were going to establish priorities and go about their business of doing risk assessments.

Well, that's very pertinent to us in California, because we have the same list to deal with. And in the report, there's some recommendations on how the prioritization might be carried out. They're just that, recommendations, but I think the bottom line was that the committee recommended that a panel of experts be convened to help EPA in setting those priorities.

So, from my point of view, that's something we want to pay particular attention to in California, is how EPA goes about that.

The second thing I would call your attention to is on the bottom of E-11 on the Executive Summary. And Hanspeter has already referred to this. And that is that EPA should quantify and communicate uncertainty in all the steps of the risk assessment process. We can see that we're starting to do that more and more in our risk assessments in connection with TACs and the law that we operate under.

But, nationally, that message, I think, has been hammered home by this committee report.

And then, finally, I guess I would point out, from my point of view, as very important, in E-12, page E-12 of the Executive Summary, one of the recommendations there

towards the bottom third of the page, it says, "EPA should aggregate cancer risk from exposure to multiple compounds." And I think the question of aggregation came up fairly frequently in the discussion. And I think it pertains to our evaluations of mixtures that we're going to be dealing with more and more here.

The only other thing that I would single out is on E-13 toward the bottom, still another recommendation was that EPA should develop the ability to conduct iterative risk assessments. So, you'd make a risk assessment today and you could come back to it later as more data becomes available and refine it with time. I think it's a fairly important recommendation, not that it isn't being done now, but I think what we're saying is that you could do a quick risk assessment for a compound that had an incomplete data set and see where you stood, and then come back and refine it later on with better data.

So, from my point of view, those were some of the highlights of the committee report.

CHAIRMAN PITTS: Dr. Glantz?

DR. GLANTZ: All I had a chance to look at was the Executive Summary at the beginning of this "telephone book."

But at the risk of being self-serving, it sounds like we're pretty much doing it the way they think it ought to be done. So, I was actually very gratified by that. And

I think it speaks well to the -- by "we," I don't just mean this committee. I think that the approach that Cal-EPA has been taking in preparing these reports is really kind of setting the trend for everybody else.

So, you guys, staff, can be very pleased. I didn't see, in just reading the Executive Summary, anything in this report that needed radical changes in the way that the process is being done here in California.

And I think to those people out there who are constantly criticizing, this is, I think, strong validation that the process is being done in a scientifically acceptable, and fair, and open way. So, I was very gratified to read this report -- or the Executive Summary.

DR. BECKER: I only had a chance to read the Executive Summary. But I was -- there's one part of it which I was unclear whether you had a chance to deal with it. I'd like to hear your comments about it.

I think all of this beautifully spelled out. But does the public really understand what's going here? And there's just this very little bit about communicating risk to the public. Is this the way -- did your committee deal with the idea of fundamentally saying, do we really understand this? Do we really communicate to the public as a whole so they really understand this?

Is the public really getting its money's worth out

of this? Did you deal with that at all?

DR. SEIBER: Well, yeah, I think so, particularly the uncertainty aspect. The general feeling was that the managers down at the -- where the rubber hits the road, had a single number and that's what they dealt with, say, in cancer potency factors. And that the range, the variability inherent in that number was not being communicated, which, of course, we've discussed here as well.

So, yeah, that was brought up many times. And I'm not sure that the Executive Summary -- there's a section on communicating risk there, but I don't think that really did justice to the volume of discussion that took place on the uncertainty? Don't you think, Peter, that that's true?

DR. WITSCHI: Well, I think the same thing happened in 1983. The committee was shunning away from giving specific directives or policy or interpretation of risk management. The committee did not want to say how things ought to be done.

DR. BECKER: Well, I think your comments were -- your comments, for instance, the difference between exposure and risk and so forth -- my overall take on it is that the public, as a whole, really doesn't understand those things. It's sort of one molecule of something is different than no molecules, and that's what -- what I liked about this was the call for prioritization. And I think you mentioned that

today, which I think is critical. We can't do everything.

You can't take 189 compounds and do risk assessments, and have people come away with any understanding of that. And I like the idea also of the iterative process. And that is that science is growing so fast that we're going to have to keep changing our knowledge of this stuff.

This is just fantastic. Actually, I think you've understated it. I think all of you are to be congratulated for making -- this will probably be more important than all the individual documents.

DR. FROINES: I just wanted to make one comment, which is not to be a skeptic. And I think it's an extremely important report. And I think it provides a basis for a lot of subsequent discussion that has to occur.

Dale Haddis and I did a study of water, drinking water in San Diego. And we found hundreds of chemicals, which you might expect, so we had to do a risk assessment based on the complex mixture. So, we were worried about uncertainty and distributional questions.

So, we did a lot of -- the way this report talks about -- we did a lot of Monte Carlo simulations and went through all the computer and mathematical formulations that were necessary to come up with looking at the uncertain in the quantitative approach to uncertainty. And so, we did

that.

The interesting thing, of course, is that when we were finished, we had a very large series of numbers. You know, when you go from "point" estimates to looking at distribution and uncertainty, you go from having a number to having many numbers. And the problem that we had when we were all finished was we had to ask ourselves, well, which ones do we use? What do we use to finally define what we consider important social benefit questions about risk?

And in the end, somebody has to define policy with respect to those issues. And I think how one goes from this stage of saying, let's look at those issues to get a better handle on risk assessment to using it for decision-making is an enormously important next step, which is going to be very difficult, because one of the problems that we've seen is that risk managers often don't have some of the technical capability to understand some of the "point" estimates that we end up coming up with. They end up drawing bright lines around a number that they not necessarily should.

So, I think this is a great first step. But I think the next step is really going to be difficult, and I think it's going to require us to develop not only priorities from a scientific context, but priorities in a social policy context/scientific policy context so we begin to know how we're going to use these numbers as we develop

them.

(Thereupon, there was a pause in the proceedings to allow the reporter to replenish her paper.)

DR. FROINES: I think we don't want to let these-- the ability to generate all these numbers become paralytic, and that we stop to try to protect people's health at large while we have much more quantitative estimates of the uncertainty in our risk assessment.

DR. WITSCHI: I think I would agree with you. But on the other hand, this was an important first step that was made to come away from the single number that came up with risk assessments before and taking them as Gospel. I think that's an important contribution.

As I said, the other one I really urge you to read, actually probably more carefully than the rest of the report, is Appendix N-1 and Appendix N-2, because that deals with something we could not come to grips, and this is how to handle the risk assessment process. And their lines were split between very conservative default assumptions on one hand or maybe a bit more -- I would not want to call it more liberal or more industry oriented, or whatever it is approach if we do not have the necessary information or scientific background for a compound.

CHAIRMAN PITTS: Are there any --

DR. FROINES: We could have great fun with this.

CHAIRMAN PITTS: Oh, yes. Well, there'll be another day.

DR. FROINES: I agree. I think it's a crucial first step.

DR. BECKER: I just want to follow up. I just happened to have been in Pennsylvania trying to describe a large study which was done about lead in these communities. And the people really aren't interested or people don't fully understand a risk assessment.

They're used to looking at a line diagram that marks your cholesterol in a certain spot, and says, this is where how old you are; this is what your cholesterol ought to be. And that's the way they look at things. They want to know if that cholesterol is good or bad, or what do we need to do about it?

And risk assessment, as we all know, has all these uncertainties built into it. And it's been really confusing for the public, because they haven't said, okay, this is normal; this is outside the normal range.

So, I think part of what's going to be needed to go into this was data on risk communication. So, once you've got all this stuff and you tell it to people, what real public impact is there here? And I think the real key to that is prioritization. Because it seems like everything is toxic, which we know depends on the dose. So, the real

question is, well, how do we deal with all of this? We need to put it into perspective for the public.

And I found that very difficult. And I did a literature search on it and found out there's no data on communicating that information to the public and then seeing, you know -- you notice asbestos is at the bottom of our chart there, when I first came on this committee, we talked about having everything on some sort of par when we look at it. Well, that wasn't very satisfactory the last time we went around. Or if you relate it to how far you drive or fly an airplane or something, none of that stuff makes any sense to people.

I was just going to put in a plea that, when you get around to it, we have to figure out how to make sure people understand what we've done here.

DR. SEIBER: It's pretty darned important, particularly in light of the newspaper articles that Dr. Pitts had sent us earlier from the L.A. Times that related to some decision-making by the South Coast Air Quality Management District. And what came out in the newspaper was 10,000 cancers are estimated based on, you know, the deliberations that took place. And what does that mean when the public sees that? I think they could become quite concerned.

DR. BECKER: That's exactly why I brought up that

point, because that's part of the confusion. I think there are ways to deal with it if it's appropriately prioritized. I think the problem is that everything seems to be toxic. It's the dose that's different. I don't know quite how to tell people how to put that in place. That's what's come to me.

DR. GLANTZ: That's one of the things that I -- I can say "I" since I got on this Panel, I think that one thing that has improved over the years is that there are these annual priority documents, and they may be based on, you know, very, very preliminary estimates. But I mean there has been an effort to steer the process towards the more important chemicals, not just the ones that are easy.

That's why, in reading this -- and you can correct me if I am wrong -- but they're describing pretty much the process that's evolved here.

DR. FRIEDMAN: Yes. I was intrigued with the recommendation that risk managers should be given characterizations of risk that are both qualitative and quantitative, i.e. both descriptive and mathematical. And because of the concerns about people just feeling that they have to operate with this, quote, "best number," did the committee come up with some specific recommendations as to present this in a qualitative way?

Because the ones we seem to look at are pretty

much quantitative. And the more information that could be given to risk managers on a qualitative basis how seriously you take this, what's the uncertainty, what does it mean, the better, I think, these reports would be.

And I just wondered if the committee had some specific recommendations about that.

DR. SEIBER: I can't remember the specifics on that. There's a chapter, Chapter 9, on uncertainty. And that's where it's dealt with, the nature of uncertainty and I think that's where that recommendation for risk managers comes out of.

So, I'd have to reread that. But I think there's some ideas in there. Whether there's practical advice, I'm not too sure. Oh, actually, when you get back to 9-15, you'll see examples -- Example 1, Example 2. And I think maybe those will give you some guidance on what the Q value means and how to communicate that to the public.

DR. WITSCHI: I think a partial answer to your question can be found on page 7-22. It is for these reasons that the committee strongly recommends that EPA include in each hazard identification portion of a risk assessment a narrative evaluation of the evidence of carcinogenicity.

And then it says, an evaluation of the strength of the available human and animal evidence, and also some written verbal evaluation of the research considered in the

risk assessment.

And I think this is also important, because if you go down to page 7-23, it's no longer good enough to say something is a carcinogen. A carcinogen is a carcinogen, because the table on page 7-23 clearly distinguishes between agents. If you find evidence of carcinogenicity in animals, you have to, you know, take a long, hard look where the people even can be exposed under circumstances which are likely to resemble those that are encountered in the animal studies. And there are clear examples. We know many of them. Just off the top of my head, you know, where they inject the material under the skin and they result in sarcomas. But, clearly, if you look at where you wouldn't encounter those methods in the real world. You would never get that injected under your own skin, and the other routes of exposure might be irrelevant.

So, I think this makes some headway along the lines you were alluding to, and just because it produces a lump in animals, does not mean it's going to produce cancer in man.

CHAIRMAN PITTS: Are there other comments?

DR. SEIBER: Yes, I just wanted to make one other comment. There's a good reason why the California experience and where we are with our risk assessment of toxic air contaminants is -- that philosophy is embodied in

this report, because the California experience was used as an example repeatedly by people in preparation of the report. You'll see a number of folks from California were on the committee. But, more importantly, we held, I believe, a workshop or two in California, so that everybody on the committee understood what had taken place in California.

So, I think you can congratulate yourselves in terms of being at the front edge of the wave. And now, the rest of the country -- if you read this document, it seems fairly obvious and bland; well, it is in California, but not necessarily in the rest of the United States.

DR. WITSCHI: Well, at our first meeting, we had presentations, and somebody said, this might look like Mt. Everest, which can only be climbed with very sophisticated gear. And so, whereas, in truth, it was rather like a hill, which could be climbed in running shoes. And the example of how it could be done was how California does it.

Obviously, the guy didn't know the geography, because the Sierra Nevada in running shoes isn't what exactly you want to do.

But, basically, he was right. He was basically saying that it has already been shown to work in California.

CHAIRMAN PITTS: Thank you. Any other comments? Well, then, I think we'll conclude.

DR. FROINES: I do have a comment. I don't think I agree with this Table 7-1 in here. We have to be very careful about, as we go leaping ahead, if we took up methylene chloride today instead of four or five years ago, we would see a very, very different level of evidence about its carcinogenicity. The National Cancer Institute, for example, recently published an epidemiologic study concerning brain cancers in humans from exposure to methylene chloride. There are other epidemiologic studies, as there are other animal data, as well as short-term testing information. So that the level of evidence has changed really quite markedly over the last three or four years. And I recently went back and looked at a 1980 document on methylene chloride that basically said it was as safe as drinking water.

So, as we move forward, we have to be very careful to understand how things change with time and maintain our -- at some level some degree of health conservatism, because things do change. And we don't want to end up sacrificing lives in that process if we can possibly avoid it.

So, I think this is extremely important. But I think we also should recognize the temporal characteristics of what we do. Things change over time and we need to be sensitive to that.

DR. WITSCHI: Yeah, I agree. With methylene

chloride, it changed from one direction. But in the federal characteristics, they're changing from --

DR. FROINES: Well, that's a very interesting question, because it goes back to something -- I think it was Jim Seiber -- about how we prioritize research so we have a broad view of what is happening with these chemicals.

When we a substance where there's a significant degree of uncertainty, I would like to see the Federal Government, EPA, say, okay, there is this uncertainty. What kind of experiments do we have to do to reduce that uncertainty; that we take a proactive stance rather than having one group go off in this direction and another group going off in this direction.

What can we do to identify whether or not the concerns about it being a carcinogen are real or not. And there are things that one can do. So, I really feel very strongly that the more we can sort of prioritize the research to address uncertainty the better off we'll be in the long run, whichever way it goes.

CHAIRMAN PITTS: Very good. Are there any other comments?

I was just going to make one final comment. I agree, it's a splendid document. The efforts that went into this are enormous. Having been involved in this panel and others of one type or another, it's a monumental task. I

appreciate your comments.

Now, I guess the last item on the agenda -- we will come to the findings. But while we're waiting for those to appear -- do you have them?

DR. DENTON: No. We can't hear you, Doctor.

CHAIRMAN PITTS: Oh, you know why you can't? I didn't push the button. Okay.

While we're waiting for the findings, let's turn to Bill Lockett. We have any suggested meeting dates and future plans? So, Bill, could you bring us up to date on where we stand?

MR. LOCKETT: Yes, Mr. Chairman and the Panel, the next gathering would be -- we're proposing it be May 13 in Southern California. This is a workshop on lead. You're all invited to come to that. That'd be the only meeting that we have on the agenda for May involving the Panel.

So, I'll go on to June, unless there's a question about May.

June, the dates that we understand would work, basically, is June 21, which is a Tuesday. Can you all still confirm that date as workable

CHAIRMAN PITTS: Yes. Would you all consult --

MR. LOCKETT: The Department of Pesticide Regulation indicates that they will have a compound for us in June of methyl parathion. It may be appropriate to

discuss what happened to the workshop in May on lead. And you may want to get an update on 1731 and AB 2728 on the hot spots and the risk assessment guidelines, et cetera.

And the next date that we understand works is also a Tuesday, July 26. I'd like you to hold that date, depending on how -- No, says Dr. Friedman.

DR. FRIEDMAN: We just received calendars now for July, August, and September. So, how did you know that July 26th would work?

MR. LOCKETT: That's a good question. I understand that an earlier poll that was taken on the phone gave us July. But maybe not.

DR. FRIEDMAN: I've had a long-term commitment for July 26th.

MR. LOCKETT: Okay. How about the 27th?

DR. FRIEDMAN: That looks okay.

MR. LOCKETT: So, it will be the 27th. Thank you very much.

CHAIRMAN PITTS: June would be in the south and July up here again?

MR. LOCKETT: Yes.

CHAIRMAN PITTS: June 21st in the south and July 27th will be either in San Francisco or Sacramento.

MR. LOCKETT: Yes.

CHAIRMAN PITTS: Any questions from the Panel on

that?

DR. FROINES: What are we doing on July 27th?

MR. LOCKETT: There's nothing scheduled at the moment. We're just trying to have that date available if we need it.

DR. GLANTZ: When do we expect lead to come back for final action?

MR. LOCKETT: That's a good question. I think it will depend on the May workshop and what derives from that. I'm advised that the earliest would be August that we'd come back with that. That's the estimate at the moment.

CHAIRMAN PITTS: Where do we stand on diesel exhaust? I have a preliminary draft of Part A, which I appreciate.

When will we get Part B?

MR. LOCKETT: I don't think we have a firm schedule on diesel exhaust other than later this year.

CHAIRMAN PITTS: Okay. Fine.

DR. FROINES: Is there going to be a workshop?

MR. LOCKETT: Yes.

MS. SHIROMA: A series of workshops.

DR. FROINES: A series of workshops.

And do you have a timetable for that?

MS. SHIROMA: Our most optimistic estimate is that we would have the workshops towards the end of summer into

the fall.

CHAIRMAN PITTS: All right. Are there any other questions?

Now, do we have -- let's go to the motion. We have sort of a modified, edited version of Dr. Seiber's motion. Would you like to read that, and then we can vote?

DR. SEIBER: The motion's been modified, and I believe you all have a copy of the retyped version. Do you want me to read the whole thing?

CHAIRMAN PITTS: Are there any questions? You might want to read it into the record.

DR. SEIBER: I'd be happy to.

CHAIRMAN PITTS: Well, go ahead. Read it into the record.

DR. SEIBER: The SRP anticipates a review of mixtures will be an important activity in connection with TACs. Accordingly, the SRP conveys its concern to ARB that there is insufficient data regarding emission sources and ambient levels in order to conduct thorough risk assessments for products of incomplete combustion, PICs, such as PAHs and their environmental transformation products.

The SRP requests that the ARB consider the availability of data and provide funding for research and/or monitoring, consistent with the availability of funding and its priority-setting process, in order to collect

information which is presently insufficient.

Examples of sources of PICs include woodburning (stoves, fireplaces, outdoor timber clearing), wildfires, agricultural burning (orchard prunings, rice stubble, et cetera), roadside weed control, as well as transportation and power generation.

That's the end.

CHAIRMAN PITTS: Comments?

DR. FRIEDMAN: I second the motion.

CHAIRMAN PITTS: Any discussion? All those in favor?

(All hands were raised.)

CHAIRMAN PITTS: Those opposed?

It's unanimously carried. Thank you very much, Dr. Seiber.

DR. SEIBER: Thank you.

CHAIRMAN PITTS: Now, have you found the findings? Ah-hah! They're coming.

Talk about timing.

(Thereupon, the draft findings were distributed to the Panel Members.)

DR. DENTON: Dr. Pitts, I'd like to mention that most of the writing on your findings is my handwriting. So, if there's something that's not clear, I probably wrote it. Also, there are two page threes, because Finding No. 9,

which is one of the ones that George rewrote, we just left it in his handwriting. So, there are two page threes.

CHAIRMAN PITTS: This is interesting. You did a good job on this. I'm glad it's your handwriting and not mine, because I can read it.

All right. Gentlemen, I presume we are going through this now, and then we can -- and each of you had comments about the different changes, and you might want to focus on those.

DR. GLANTZ: Looks good to me.

CHAIRMAN PITTS: This is truly a working document. I like it. Great.

Just one little very minor change on 9. You say, "Epidemiologic evidence for carcinogenic effects of BaP," do you want to say BaP "alone"?

DR. ALEXEEFF: Yes.

CHAIRMAN PITTS: Just add "alone" to that.

DR. BECKER: I make a motion that we accept that word "alone."

CHAIRMAN PITTS: Is there a second to the motion?

DR. GLANTZ: I second it.

CHAIRMAN PITTS: George?

DR. ALEXEEFF: Dr. Witschi had one other correction on No. 10, alkylate to arylate.

DR. BECKER: With those two changes, I make a

motion that we accept the findings with the alone and the arylate.

DR. GLANTZ: I second it.

CHAIRMAN PITTS: Any discussion? All those in favor, aye?

(All hands were raised.)

CHAIRMAN PITTS: Opposed? Unanimously approved. Thanks very much.

I appreciate you modified these and the time and effort that went into this.

Are there other comments? Yes.

MS. SHIROMA: You asked that several revisions be made to the Part A and B documents. And did you want us to work with you on those changes and we'll take a look at the transcript, and then finalize them, or did you want the whole panel to look at those?

DR. GLANTZ: The Chair.

MS. SHIROMA: We could work with you, Dr. Pitts?

CHAIRMAN PITTS: Work with me, and, if necessary, we'll tape somebody on the panel.

MS. SHIROMA: Fine. Thank you.

CHAIRMAN PITTS: Well, thanks very much to the staff of all sides, the ARB and the OEHHA. You did a find job, and it worked out well, and appreciate the effort.

We stand adjourned.

(Thereupon, the Scientific Review Panel was adjourned at 1:00 p.m.)

--o0o--

CERTIFICATE OF SHORTHAND REPORTER

--o0o--

I, Nadine J. Parks, a shorthand reporter of the State of California, do hereby certify that I am a disinterested person herein; that the foregoing meeting of the Scientific Review Panel was reported by me in shorthand writing, and thereafter transcribed into typewriting.

I further certify that I am not of counsel for any of the parties to said meeting, nor am I interested in the outcome of said meeting.

IN WITNESS WHEREOF, I have hereunto set my hand this 29th of April, 1994.

Nadine J. Parks

Nadine J. Parks

Shorthand Reporter